

REMARKS

I. Status of the Application

Claims 25-27 and 29-52 are pending in the application. Claims 39 and 44-46 have been cancelled without prejudice to the filing of any appropriate continuation applications. Claims 25, 27, 29, 32-34, 37, 40, 44, 45, and 48-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., U.S. Patent No. 4,141,783, in view of Badertscher, GB 2 036 534, further in view of Den Hollander, U.S. Patent No. 5,558,819. Claims 26, 30 and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Rubens, EP 0 438 783. Claims 35 and 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Arndt, U.S. Patent No. 3,843,828. Claim 38 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Bond et al., U.S. Patent No. 5,210,958. Claims 39 and 46 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Scott et al., U.S. Patent No. 3,925,560. Claim 41 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Bond et al., U.S. Patent No. 5,210,958. Claim 42 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher, Den Hollander and Bond et al., further in view of Hovmand et al., U.S. Patent No. 4,062,641. Claim 43 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Johnston, U.S. Patent No. 2,401,077. Claim 47 stands rejected under 35 U.S.C. §103(a) as being

unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Bosund et al., U.S. Patent No. 4,091,003.

Applicant has amended the claims under consideration to more clearly define and distinctly characterize Applicant's novel invention. Specifically, claim 25 was amended to recite "so as to kill microorganisms and produce a pasteurized or sterilized liquid," support for which can be found at least at page 5, lines 7-16 of the instant specification, where Applicant teaches pasteurizing or sterilizing a liquid and that pasteurizing or sterilizing kills microorganisms. Claim 25 was further amended to recite "wherein after drying into powder form having a primary particle size of 10 to 60 μm , the powdered form of the pasteurized or sterilized liquid is reconstitutable into a liquid food product suitable for infant consumption," support for which can be found in the specification at least at page 15, lines 24 and 25, where Applicant teaches a powdered product having a primary particle size of 10-60 μm ; at page 14, where Applicant teaches reconstitution; and at page 6, line 18, where Applicant teaches infant foods. Claims 48-50 were amended to address formal matters.

Applicant respectfully submits that the amendments presented herein do not raise new issues requiring further search, and add no new matter. Applicant respectfully requests entry and consideration of the foregoing amendments, which are intended to place the case in condition for allowance or at least in better condition for appeal.

II. The Pending Claims are Nonobvious over the Cited Art

At page 2, section 3 of the instant Office Action, claims 25, 27, 29, 32-34, 37, 40, 44, 45, and 48-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., U.S.

Patent No. 4,141,783, in view of Badertscher, GB 2 036 534, further in view of Den Hollander, U.S. Patent No. 5,558,819. At page 5, section 4 of the instant Office Action, claims 26, 30 and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Rubens, EP 0 438 783. At page 6, section 5 of the instant Office Action, claims 35 and 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Arndt, U.S. Patent No. 3,843,828. At page 7, section 6 of the instant Office Action, claim 38 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Bond et al., U.S. Patent No. 5,210,958. At page 7, section 7 of the instant Office Action, claims 39 and 46 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Scott et al., U.S. Patent No. 3,925,560. At page 8, section 8 of the instant Office Action, claim 41 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Bond et al., U.S. Patent No. 5,210,958. At page 8, section 9 of the instant Office Action, claim 42 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher, Den Hollander and Bond et al., further in view of Hovmand et al., U.S. Patent No. 4,062,641. At page 9, section 10 of the instant Office Action, claim 43 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Johnston, U.S. Patent No. 2,401,077. At page 9, section 11 of the instant Office Action, claim 47 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al., in view of Badertscher and Den Hollander, further in view of Bosund et al., U.S. Patent No.

4,091,003. Applicant respectfully traverses these rejections based on the amended claims now presented.

The pending claims are directed in part to a method for pasteurizing or sterilizing a product in liquid form which, after drying into *powder form* having a *primary particle size of 10 to 60 μm* , is reconstitutable into a *liquid food product suitable for infant consumption*. Applicant's claimed method is suitable for preparing a pasteurized or sterilized product containing heat sensitive substances having high quality and high biological activity, such as infant food (page 2, lines 7-9; page 6, lines 16-18). The dried powder having the claimed primary particle size achieved using Applicant's claimed method has very good wettability and dissolution behavior and accordingly, is particularly suitable for use as infant food (page 15, lines 17-18).

A. The combination of Pisecky et al., Badertscher and Den Hollander fails to render the claimed invention obvious.

The primary reference, Pisecky et al., fails to teach or suggest each and every element of the claimed invention. Pisecky et al. is directed to a spray drying atomizer wheel that degasifies a liquid composition prior to atomization on order to reduce air inclusion in the final product (column 1, lines 1-40; column 2, line 62 to column 3, line 2). Pisecky et al. fails to teach or suggest Applicant's claimed primary particle size, and this is admitted in the instant Office Action (page 7, section 7). Further, Pisecky et al. fails to teach or suggest that their powders are reconstitutable into a liquid food product suitable for infants.

Nowhere does Pisecky et al. teach a suitable infant food, e.g., formula. Although the instant Office Action states that powdered milk is infant food, Applicant respectfully disagrees. Commercially available milk is not suitable for use as infant food. The American Academy of

Pediatrics issued a statement in 1992 that whole cow's milk not be used during the first year of life (See Attachment A). It was determined that "[i]nfants fed whole cow's milk receive inadequate amounts of Vitamin E, iron, and essential fatty acids. They also receive excessive amounts of protein, sodium, and potassium. These levels may be too high for the infant's system to handle. Additionally, whole cow's milk protein and fat are far more difficult for an infant to absorb...[r]ecent studies show infants often have depleted levels [of iron] when started on cow's milk at six months of age." (Attachment A). Clearly, the powdered milk of Pisecky is not a liquid food product suitable for infants, as claimed by Applicant.

Further, methods of spray drying a liquid product having a high solids content known in the art at the time of filing often resulted in the formation of gelatinized starch in the final product. Reconstitution of a composition including gelatinized starch results in a product that is not uniformly liquid upon reconstitution and accordingly, would not be suitable as infant food. In contrast, the reconstitutable nature of Applicant's dried powder makes it particularly suitable for use as an infant food as it is easily dissolvable into liquid form.

For at least these reasons Pisecky et al. fails to teach or suggest each and every element of Applicant's claimed method. Badertscher and Den Hollander fail to cure the deficiencies of Pisecky et al.

Badertscher is directed to an apparatus for injecting steam into a fluid such that sterilization or homogenization occurs (first paragraph). Badertscher fails to teach or suggest Applicant's claimed primary particle size, and the instant Office Action notes this fact (page 7, section 7). Further, Badertscher fails to teach or suggest powders that are reconstitutable into a liquid food product suitable for infants. In fact, at Example 6, Badertscher teaches a product to

be sterilized having a dry matter content of 60% prepared from 50% of cereal flour. A composition having such a high percentage of cereal, which is mostly starch, would likely gelatinize upon spray drying, thus producing a product that is not uniformly liquid upon reconstitution and, accordingly, unsuitable as infant food.

Den Hollander is directed to a plant for heating a free-falling liquid in a pressure chamber (abstract). Den Hollander fails to teach or suggest Applicant's claimed primary particle size, and this fact is acknowledged by the instant Office Action (page 7, section 7). Further, Den Hollander fails to teach or suggest powders that are reconstitutable into a liquid food product suitable for infants.

Accordingly, the combination of Pisecky et al., in view of Badertscher, further in view of Den Hollander fails to teach or suggest each and every element of the claimed invention.

B. The combination of Pisecky et al., Badertscher, Den Hollander and Scott fails to render the claimed invention obvious.

The Office Action states that although Pisecky et al., Badertscher and Den Hollander all fail to teach the average value range for the diameter of dried particles, Scott teaches that after spray-drying the liquid product, the particles have a diameter between 10-60 micrometers (page 7, section 7). The Office Action concludes that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Pisecky's process by including a spray-drying step after steam sterilization that produces particles with diameters between 10 to 60 micrometers as taught by Scott at column 5, lines 4 and 5, in order to form voids in the particles resulting in added advantage. Applicant respectfully disagrees.

Applicant respectfully submits that one of skill in the art, based on the teachings of the cited references *as a whole*, would fail to arrive at the claimed invention. "A prior art reference

must be considered in its entirety, i.e., as a whole, ***including portions that would lead away from the claimed invention***” (MPEP §2141.02(VI), emphasis added, citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)). The teachings of Pisecky et al., as a whole, would not motivate one of skill in the art to modify the teachings as asserted by the Office Action and would, in fact, ***teach away*** from combining these two references. At column 5, lines 4-10, Scott teaches ***hollow spheres*** that are 10-60 μ in diameter. Although the Office Action states that it would be advantageous to form such voids in the particles, the teachings of Pisecky et al. are at odds with such a motivation to combine.

Pisecky et al. teaches many ***disadvantages of particles containing voids***. Pisecky et al. teaches that conventional spray drying techniques produce powder having a large volume of vacuoles and, accordingly, a low bulk density which necessitates the use of large containers which are made from large amounts of container material and require a large amount of space when shipping (column 1, lines 22-30). Further, Pisecky et al. teaches that occluded air can cause the troublesome formation of foam when the powder is reconstituted (column 1, lines 32-33). Pisecky et al. teaches that powder having vacuoles is also vulnerable to harmful oxidation and absorption of humidity which necessitates storage under inert gas or in a vacuum (column 1, lines 34-40). Pisecky then states that their invention “aims at more effectively ***obviating the disadvantages*** mentioned in the foregoing which are ***due to the air content or air inclusion***” and teach a method of ***minimizing the volume of occluded air*** (column 2, lines 62-64 and column 4, lines 3-9, emphasis added). Based on the teachings of Pisecky et al., one of skill in the art would not look to Scott to modify the methods of Pisecky et al. to arrive at the claimed invention.

Accordingly, the combination of Pisecky et al., Badertscher, Den Hollander and Scott fails to render the claimed invention obvious.

C. Any combination of cited references fails to render the claimed invention obvious.

None of the remaining references, alone or in combination fails to cure the deficiencies of the references discussed above.

Rubens fails to cure the deficiencies of Pisecky et al., Badertscher, Den Hollander and Scott. Rubens is directed to a method of cooking and spray-drying a starch (abstract). Rubens fails to teach or suggest Applicant's claimed primary particle size or powders that are reconstitutable into a liquid food product suitable for infants.

Arndt fails to cure the deficiencies of Pisecky et al., Badertscher, Den Hollander and Scott. Arndt is directed to methods of blending sweet dairy whey and an isolated, non-animal protein using a specific heat and pressure treatment (column 2, lines 8-38). Arndt fails to teach or suggest Applicant's claimed primary particle size or powders that are reconstitutable into a liquid food product suitable for infants.

Bond et al. fails to cure the deficiencies of Pisecky et al., Badertscher, Den Hollander and Scott. Bond et al. is directed to a method and apparatus for drying paper by passing a wet paper web over a series of cylinders containing saturated steam (column 1, lines 7-14). Bond et al. fails to teach or suggest Applicant's claimed primary particle size or powders that are reconstitutable into a liquid food product suitable for infants.

Hovmand et al. fails to cure the deficiencies of Pisecky et al., Badertscher, Den Hollander and Scott. Hovmand et al. is directed to an agglomerating unit having a rotatable, conical,

downwardly, narrowing section on the interior surface of which moistened powder is deposited (abstract). Hovmand et al. fails to teach or suggest Applicant's claimed primary particle size.

Johnson fails to cure the deficiencies of Pisecky et al., Badertscher, Den Hollander and Scott. The Johnston reference is directed to a method for sterilizing liquids such as milk and milk products (page 2, left column, lines 3-7). Johnson fails to teach or suggest Applicant's claimed primary particle size or powders that are reconstitutable into a liquid food product suitable for infants.

Bosund et al. fails to cure the deficiencies of Pisecky et al., Badertscher, Den Hollander and Scott. Bosund et al. is directed to a process for preparing a protein isolate from fish material (abstract). Bosund et al. fails to teach or suggest Applicant's claimed primary particle size or powders that are reconstitutable into a liquid food product suitable for infants.

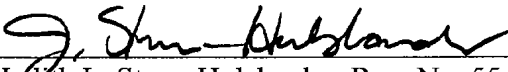
Thus, the combination of references fails to teach or suggest the claimed invention. Accordingly, Applicant respectfully requests that rejection of claims 25-37 and 29-52 under 35 U.S.C. §103(a) as being unpatentable over various combinations of the cited references be reconsidered and withdrawn.

III. Conclusion

Having addressed all outstanding issues, Applicant respectfully requests reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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Medical Encyclopedia: Cow's milk for infants and children

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Definition

In 1992, the American Academy of Pediatrics released their statement regarding the use of whole cow's milk during infancy. The findings were published in "Pediatrics" volume 89, number 6 in June of 1992. Plainly stated, the Academy recommended that whole cow's milk and low-iron formulas not be used during the first year of life.

Infants fed whole cow's milk receive inadequate amounts of Vitamin E, iron, and essential fatty acids. They also receive excessive amounts of protein, sodium, and potassium. These levels may be too high for the infant's system to handle. Additionally, whole cow's milk protein and fat are more difficult for an infant to digest and absorb.

The most dramatic effects are on iron levels in the body. Infants fed breast milk or iron fortified formula have normal iron levels. Recent studies show infants often have depleted levels when started on cow's milk at six months of age.

Optimal nutrition in an infant involves selecting the appropriate milk source and eventually introducing the infant to solid foods. In achieving this goal, the American Academy of Pediatrics recommends that infants be fed breast milk or iron-fortified formula during the first twelve months of life. Between the ages of four to six months, appropriate solid foods may be added. Taking breast milk or iron-fortified formula, along with the age-appropriate solid foods and juices during the first year of life, allows for more balanced nutrition.

Recommendations

Skim or 2% milk:

Under one year of age, skim and 2% (low-fat) milk have no place in the diet. They supply too much protein, potassium, and sodium and not enough calories for the growing infant. Children also need the fat for proper growth and development including brain development.

Low fat milks are not the answer for an overweight baby. The desirable diet is the same as that of a normal weight infant; the amount is the only difference. Conferring with a registered dietitian or physician is recommended. The recommendation will probably be a reduction in the amount of intake, not the type of intake. A slight reduction of calories by reducing the amount will allow the infant to "grow into his weight" without a rapid change in body fat. Rapid weight loss can be dangerous, particularly in a small child. An extreme reduction of fat stores might not leave enough energy stores for the infant to combat a serious illness. Many physicians question the serious, unknown consequences of a rapid loss of fat.

Suggested Intake - Infants:

- Breast Milk:
 - every 1-3 hrs for infants 0-3 months
 - every 2-4 hrs for infants 4-5 months
 - every 3-4 hrs for infants 6-8 months
 - every 4-5 hrs for infants 9-12 months
- Iron fortified Formula (per day):

- 18-40 oz. for infants 0-3 months
- 24-45 oz. for infants 4-5 months
- 24-37 oz. for infants 6-8 months
- 24-31 oz. for infants 9-12 months
- Dairy:
 - none for infants 0-3 months
 - none for infants 4-5 months
 - none for infants 6-8 months
 - small servings for infants 9-12 months

Suggested intake - children 2 to 5 years of age:

- cow's milk
 - 6 servings/day
 - one servings equals:
 - 1/2 cup milk, yogurt, pudding
 - 3/4 oz. cheese
 - 1 cup cottage cheese

Suggested intake - teens and adults (The equivalent of one of the following is recommended):

- milk/yogurt (1 cup)
 - 3-4 servings/day
- 1 1/2 oz. natural cheese
 - 2-3 servings/day
- 2 oz. processed cheese
 - 4 servings/day

See also: infant formulas

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Updated by: Daniel Rauch, MD, FAAP, Director, Pediatric Hospitalist Program, Associate Professor of Pediatrics, NYU School of Medicine, New York, NY.

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